DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 20

[Docket No. 2004N–0214]

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Certifier A. Corbin

Public Information Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its public information regulations to implement more comprehensively the exemptions contained in the Freedom of Information Act (FOIA). This action incorporates exemptions one, two, and three of FOIA into FDA's public information regulations. Exemption one applies to information that is classified in the interest of national defense or foreign policy. Exemption two applies to records that are related solely to an agency's internal personnel rules and practices. Exemption three incorporates the various nondisclosure provisions that are contained in other Federal statutes. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under the agency's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comments and withdraws this direct final rule.

DATES: The rule is effective [*insert date 135 days after date of publication in the* **Federal Register**]. Submit written or electronic comments by [*insert date 75 days after date of publication in the* **Federal Register**]. If FDA receives no significant adverse comments by the specified comment period, the agency will

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publish a document in the **Federal Register** confirming the effective date of this direct final rule. If the agency receives any significant adverse comments during the specified comment period, FDA intends to withdraw this direct final rule before its effective date by publication of a document in the **Federal Register**.

ADDRESSES: You may submit comments, identified by [Docket No. 2004N–0214], by any of the following methods:

Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

E-mail: *fdadockets@oc.fda.gov*. Include [Docket No. 2004N–0214] in the subject line of your e-mail message.

FAX: 301–827–6870.

Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. 2004N–0214 for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the

Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Betty B. Dorsey, Division of Freedom of Information (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6567.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is amending its public information regulations to incorporate exemptions one, two, and three of the FOIA (5 U.S.C. 552). FOIA provides that all Federal agency records shall be made available to the public upon request, except to the extent those records are protected from public disclosure by one of nine exemptions (5 U.S.C. 552(b)) or one of three special law enforcement record exclusions (5 U.S.C. 552(c)). FDA originally issued its public information regulations implementing FOIA in 1974. As noted at the time, FDA's 1974 regulations explicitly addressed four of the nine FOIA exemptions that were then perceived to be of particular importance to the agency, those relating to trade secrets, internal memoranda, personal privacy, and investigatory files (39 FR 44602, December 24, 1974). FDA now finds it necessary to address exemption one (5 U.S.C. 552(b)(1)), given the President's designation of the Secretary of Health and Human Services to classify information under Executive Order 12958 (66 FR 64347, December 12, 2001). Because exemption two (5 U.S.C. 552(b)(2)) applies to, among other types of records, internal matters whose disclosure would risk circumvention of a legal requirement, this exemption is of fundamental importance to homeland security in light of recent terrorism events and heightened security awareness. In addition, FDA now finds that exemption three (5 U.S.C. 552(b)(3)), which

incorporates the various nondisclosure provisions that are contained in other Federal statutes, is becoming increasingly important to the agency. As such, FDA is amending, by direct final rule, subpart D of its public information regulations in 21 CFR part 20 to incorporate these three exemptions.

II. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. This direct final rule amends the agency's public information regulations by incorporation of exemptions one, two, and three of FOIA, which have become increasingly relevant to FDA and its records. Because these exemptions are already contained in FOIA, this action should be noncontroversial, and the agency does not anticipate receiving any significant adverse comments on this rule.

If FDA does not receive significant adverse comments during the specified comment period, the agency will publish a document in the **Federal Register** confirming the effective date of this direct final rule (see **DATES**). A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or why it would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment states why this rule would be ineffective without the additional change. If timely significant adverse comments are received, the agency will publish a document of significant adverse comment in the **Federal Register** withdrawing this direct final rule.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, identical to the direct final rule, that provides a procedural framework within which the proposed rule may be finalized in the

event the direct final rule is withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule and the agency will consider such comments in developing a final rule. FDA will not provide additional opportunity for comment on the companion proposed rule.

If a significant adverse comment applies to an amendment, paragraph, or section of this direct final rule and that provision may be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment. A full description of FDA's policy on the direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not

contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. Analysis of Impacts

FDA has examined the impacts of the direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this direct final rule simply incorporates three existing FOIA exemptions, the agency certifies that it will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million, adjusted annually

for inflation. As noted previously, we find that this final rule would not have an effect of this magnitude on the economy.

VI. Paperwork Reduction Act of 1995

The direct final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 20 is amended as follows:

PART 20—PUBLIC INFORMATION

■ 1. The authority citation for part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

■ 2. Section 20.65 is added to read as follows:

§ 20.65 National defense and foreign policy.

(a) Records or information may be withheld from public disclosure if they are:

(1) Specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy; and

(2) In fact properly classified under such Executive order.

(b) [Reserved]

■ 3. Section 20.66 is added to read as follows:

§ 20.66 Internal personnel rules and practices.

Records or information may be withheld from public disclosure if they are related solely to the internal personnel rules and practices of the Food and Drug Administration (FDA). Under this exemption, FDA may withhold records or information about routine internal agency practices and procedures. Under this exemption, the agency may also withhold internal records whose release would help some persons circumvent the law.

■ 4. Section 20.67 is added to read as follows:

§ 20.67 Records exempted by other statutes.

Records or information may be withheld from public disclosure if a statute specifically allows the Food and Drug Administration (FDA) to withhold them. FDA may use another statute to justify withholding records and information

only if it absolutely prohibits disclosure, sets forth criteria to guide our decision on releasing material, or identifies particular types of matters to be withheld.

Dated: 8/24/04
August 24, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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